

REMARKS

Reconsideration of the present application is respectfully requested. An objection was raised to the specification, and specifically to the Description of the Figures. Applicants have amended the description of FIG. 9 to change the reference from FIG. 7 to FIG. 8, which is consistent with the actual figures.

Objections were raised to the drawings that Applicants have corrected by amendments to the specification. One ground of objection was that the reference numbers 65 and 87 were found in the specification but not in the figures. In the original specification, applicants had used the reference numbers 65 and 87 as a short-hand designation for the features 65_U, 65_L found in FIG. 5 and features 85_U, 85_L found in FIG. 9. In the face of this objection, Applicants have amended the specification at pages 14 and 15 to replace these short-hand designations to refer to the appropriate feature numbers found in the figures.

The second ground of objection to the drawings was directed to reference numbers 81 and 89 which are present in FIG. 9 but not in the specification. Accordingly, Applicants have added a sentence describing each feature depicted in FIG. 9. These features are apparent from the figure and Applicants have added no new matter by providing a brief description of these two feature.

In view of these corrections to the specification it is believed that all objections to the drawings have been addressed. Thus, there is no need to amend the figures.

Claims 1-8 and 15-20 were rejected as anticipated by U.S. Patent No. 5,380,325 to Lahille et al. Claim 1 has been amended to define the one connector as supporting the flexible element between the bone anchor and the stabilization element along the longitudinal axis of the element. In contrast, the Lahille device employs a connecting means 3 that clamps onto the rod and supports the bone screw 3 laterally offset from the rod and the longitudinal axis of the rod. All of the embodiments depicted in the Lahille patent relies upon the

clamping mechanism between split halves of the connector 3 so that only the clamping mechanism of the connector may be disposed along the longitudinal axis of the rod. The Lahille clamping mechanism necessitates that the screw 3 be laterally offset from the rod. Since the damping means or washer arrangement 25 of Lahille is supported exclusively by the shank 22 of the screw, the washer arrangement must also be laterally offset from the rod and its longitudinal axis.

Applicants' claimed invention provides that the flexible element that permits adjustable relative pivoting between the bone anchor and the stabilization element is supported along the longitudinal axis of the stabilization element. Whether the stabilization element is a rod, as shown in FIGS. 2-7, or a plate, as shown in FIGS. 8-9, the flexible element is disposed along a longitudinal axis of the element, and not transverse to the element as in the Lahille device. Thus, Applicants' claimed invention eliminates the additional degree of freedom of movement that arises between the Lahille clamp and the rod.

The Lahille patent does not disclose a flexible element that is supported along the longitudinal axis of the stabilization element. Thus, Lahille cannot anticipate Applicants' claim 1 as currently written. Moreover, since the Lahille device requires a slotted connector that must clamp around the rod, this patent does not contemplate any means for supporting the washer arrangement 25 along the longitudinal axis of the rod. Consequently, it is believed that claim 1 as amended is novel and non-obvious in view of the Lahille reference.

Each of the dependent claims 2-8 benefit from the allowability of their parent claim 1. Moreover, these claims are patentable on their own merits. For instance, claim 2 defines the connector as including a bearing member attached to the stabilization element. There is nothing in Lahille that identifies the split clamp 3 as a bearing member as it is known in the art. Claim 3 further defines

this bearing member as a rod end bearing. Again, there is nothing in Lahille that shows a rod end bearing as this term is understood in the art.

Applicants' claim 4 depends from claim 3 and further recites that the bearing element is received within a bearing race. The flat washers 26 were identified in the Office Action as constituting a bearing race. However, this identification is clearly at odds with the known meaning of the term "bearing race" in the art. There is no bearing race in the Lahille device, as that term is known in the art.

Claims 15-20 were also rejected as anticipated by the Lahille patent. This claim defines the one connector as including a bearing member and a bearing race. To help clarify the recited structure, Applicants have amended claim 15 to indicate that the bearing race is mounted within the bearing member. The flexible bearing element is mounted within the bearing race.

As explained above, the Lahille patent does not disclose a bearing member, a bearing race or the flexible bearing element being mounted within a bearing race. The Office Action incorrectly referred to the Lahille washer arrangement 25, 26 as corresponding to this combination of elements. The Lahille elements 26 are simply flat washers. They do not constitute a bearing member and certainly do not constitute a bearing race as this term is conventionally understood in the art. At best, these washers 26 provide a pressure interface between the flexible washer 25 and either the clamp 3 or the bone screw 2 so the washer doesn't "flow" into or around these components. There is nothing in the Lahille patent that contemplates or suggests any relative movement between the flexible washer 25 and the adjacent flat washers 26.

In contrast, as is known in the art, a bearing member contemplates relative movement between the components of the bearing, and in particular between the bearing race and the bearing element mounted within the bearing race. In the case of Applicants' invention, the bearing element is the flexible

bearing element. There is nothing in the Lahille patent that discloses or contemplates a bearing member, a bearing race, or a flexible bearing element mounted within a bearing race. Thus, the Lahille patent cannot anticipate or render obvious Applicants' invention recited in claim 15, or in the dependent claims 16-20.

Concurrent with this response Applicants have submitted a Supplemental Information Disclosure Statement and accompanying Form 1449 to cite the following patent publications that have recently come to Applicants' attention: 5,304,179; 6,001,130; 6,986,771; 6,989,011; and US 2002/0026194. It is believed that none of these references discloses the spinal stabilization system defined in Applicants' claims. The Paul reference disclose a spinal stabilization system that accommodates motion between adjacent vertebrae but appears to do so through the construction of the elongated element itself, rather than through a connector engaging the bone screw to the elongated element. The Bryan reference shows a disc prosthesis with a prosthetic ligament that controls relative movement between adjacent vertebrae. The Wagner patent shows a rod end coupling arrangement with variable angle bushings. However, the bushings do not appear to be flexible or compressible. The published application of Morrison et al. appears to disclose a system for multi-axial mounting of a bone bolt to a spinal plate. However, not of the washers used for this mounting appear to be flexible or resilient or capable of permitting and controlling relative movement between the plate and the bone bolts.

In view of the foregoing arguments, it is believed that Applicants invention of claims 1-8 and 15-20 is patentable over the art of record. In this Office Action, claims 9-14 were withdrawn as drawn to a non-elected species. It was suggested in the Office Action that there was no allowable generic or linking claim. It was acknowledged that claims 1, 2, 6 and 7 are generic claims. Since

each of these claims is believed to be allowable, it is requested that claims 9-14, all of which depend directly or indirectly from claim 1, be reinstated.

Action toward allowance of the present application is requested. The Examiner is invited to contact the undersigned agent of record if it is believed that a telephonic interview may help place this application in condition for allowance.

Respectfully submitted,



Michael D. Beck
Maginot, Moore & Beck, LLP
111 Monument Circle, Suite 3250
Indianapolis, Indiana 46204
(317) 638-2922